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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/587,052

04/09/2007

Paul A. Bunn Jr.

2848-65-PUS

7009

22442

7590

11/29/2007

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EXAMINER

AEDER, SEAN E

ART UNIT

PAPER NUMBER

1642

MAIL DATE

DELIVERY MODE

11/29/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/587,052

Applicant(s)

BUNN JR. ET AL.

Examiner

Sean E. Aeder

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 47-65 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 47-65 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 47-59, drawn to methods of selecting a patient who is predicted to benefit from an EGFR inhibitor comprising detecting expression of one or more genes selected from the group consisting of SEQ ID NOs:1-194.

Group II, claim(s) 60-64, drawn to methods to identify a compound with the potential to enhance the efficacy of EGFR inhibitors comprising contacting a test compound with a cell that expresses one or more nucleic acid sequences selected from the group consisting of SEQ ID NOs:1-194.

Group III, claim(s) 65, drawn to methods of treating a patient comprising administering a compound that upregulates the expression of E-cadherin, upregulates the activity of E-cadherin, upregulates the expression of ErbB3, upregulates the activity of ErbB3, upregulates the expression of the gene encoding E-cadherin, upregulates the activity of the gene encoding E-cadherin, upregulates the expression of the gene encoding ErbB3, upregulates the activity of the gene encoding ErbB3, downregulates the expression of ZeB1, downregulates the expression of SIP1, downregulates the expression of the gene encoding ZeB1, or downregulates the expression of the gene encoding SIP1.

The inventions listed as groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking groups I-III appears to be that they all relate to the special technical feature of methods comprising ErbB3 and compounds of therapeutic treatments.

However, Knowlden et al (Oncogene, 1999, 17:1949-1957) teaches methods comprising ErbB3 compounds of therapeutic treatments (see left column of page 1954, in particular).

Therefore, the technical feature linking the inventions of groups I-III does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art.

Accordingly, groups I-III are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.

### ***Species***

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Claims 47-59 are generic to a plurality of disclosed patentably distinct species of **"methods comprising detecting and comparing expression of specific combinations of genes selected from the group consisting of SEQ ID NOs:1-194"**. The following are examples of species encompassed by methods comprising detecting and comparing expression of specific combinations of genes selected from the group consisting of SEQ ID NOs:1-194: methods comprising detecting and comparing expression of SEQ ID NOs:1, 2, and 3; methods comprising detecting and comparing expression of SEQ ID NO:14; and methods comprising detecting and comparing expression of SEQ ID NOs:1-10. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The methods of the above species differ at least in objectives, method steps, reagents, response variables, and criteria for success such that one species could not be interchanged with the other. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Claims 60-64 are generic to a plurality of disclosed patentably distinct species of **"methods comprising contacting cells that express one or a specific combination of genes selected from SEQ ID NOs:1-194"**. The following are examples of species encompassed by methods comprising contacting cells that express one or a specific combination of genes selected from SEQ ID NOs:1-194: methods comprising contacting cells that express SEQ ID NOs:1, 2, and 3; methods comprising contacting cells that express SEQ ID NO:14; and methods comprising contacting cells that express SEQ ID NOs:1-10. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The methods of the

above species differ at least in objectives, method steps, reagents, response variables, and criteria for success such that one species could not be interchanged with the other. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Claim 65 is generic to a plurality of disclosed patentably distinct species of **"methods of administering a compound"** comprising the following: methods of administering a compound that upregulates the expression of E-cadherin; methods of administering a compound that upregulates the activity of E-cadherin; methods of administering a compound that upregulates the expression of ErbB3; methods of administering a compound that upregulates the activity of ErbB3; methods of administering a compound that upregulates the expression of the gene encoding E-cadherin; methods of administering a compound that upregulates the activity of the gene encoding E-cadherin; methods of administering a compound that upregulates the expression of the gene encoding ErbB3; methods of administering a compound that upregulates the activity of the gene encoding ErbB3; a compound that downregulates the expression of ZeB1; methods of administering a compound that downregulates the expression of SIP1; methods of administering a compound that downregulates the expression of the gene encoding ZeB1; and methods of administering a compound that downregulates the expression of the gene encoding SIP1. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The methods of the above species differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success such that one species could not be interchanged with the other. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean E. Aeder, Ph.D. whose telephone number is 571-272-8787. The examiner can normally be reached on M-F: 8:30-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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